



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,008	11/25/2003	Fu-Pao Tsao	CL/V-32800A	6999

1095 7590 01/04/2006

NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER

OGDEN JR, NECHOLUS

ART UNIT PAPER NUMBER

1751

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/722,008

Applicant(s)

TSAO ET AL.

Examiner

Necholus Ogden

Art Unit

1751

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 25-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/03;6/04.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 12-27-05.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-24 are, drawn to a composition, classified in class 510, subclass 112.
  - II. Claims 25-30, drawn to a method of cleaning, classified in class 514, subclass 23.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as tanning hides or cleaning leather.
3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Jian Zhou on November 3, 2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-24. Affirmation of this election must be made by applicant in replying to this

Art Unit: 1751

Office action. Claims 25-30 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### **DETAILED ACTION**

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language:

#### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1751

8. Claims 1-12-14, 16-19, 21 and 23 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schwind et al (2002/0155961).

Schwind et al disclose a lens care product comprising 5-20 g/l of dexpanthenol; 10 to 30 g/l of D-sorbitol; 0 to 5 g/l of sodium chloride or potassium chloride; 0.0005 to 0.05 g/l of PHMB; 0.1 to 2 g/l of EDTA; disodium phosphate buffers; water; a surface active substance; viscosifier; a pH value of 6 to 8 (see 0030-0032) and 0.072 g/l of disodium hydrogen phosphate (0039). Schwind et al further teach that the tonicity is measured in the range of 200 to 450 milliosmol (col. 1, 0007).

As this reference teaches all of the instantly required it is considered anticipatory.

Alternatively, Schwind et al is silent with respect to reducing the *C. albicans* within 15 minutes and having a log reduction of at least 1 or 1.5. However, it would have been obvious to the skilled artisan in the contact lens disinfecting art to expect the compositions of Schwind et al to encompass the *C. albicans* in the requisite log reduction and time of contact because Schwind et al teaches all of the claimed components for the purpose of disinfecting and absent a showing to the contrary one of ordinary skill would expect similar contact lens cleaning and disinfecting characteristics.

9. Claims 1-8, 11-12, 14-15, 17-20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Groemminger et al (6,872,695).

Groemminger et al disclose a method of cleansing contact lens comprising a thickening agent such as PVP (col. 4, line 42); surfactants such as polyaxamine and

Art Unit: 1751

tyloxapol (col. 4, line 66 and col. 5, line 35); an antimicrobial such as PMHB in an amount from 0.00001 to 5%; osmolality-adjusting agent such as glycerol to provide osmolality of 270 mOsm/kg and a pH of 5-6 (col. 6, lines 26-59); a sequestering or chelating agent such as EDTA (col. 6, lines 60-62) and tonicity agents such as sodium chloride in amount from 0.01 to 2.5% (col. 7, lines 1-11).

As this reference teaches all of the required, it is considered anticipatory.

Alternatively, Groemminger et al is silent with respect to reducing the *C. albicans* within 15 minutes and having a log reduction of at least 1 or 1.5. However, it would have been obvious to the skilled artisan in the contact lens disinfecting art to expect the compositions of Groemminger et al to encompass the *C. albicans* in the requisite log reduction and time of contact because Groemminger et al teaches all of the claimed components for the purpose of disinfecting and absent a showing to the contrary one of ordinary skill would expect similar contact lens cleaning and disinfecting characteristics.

***Claim Rejections - 35 USC § 103***

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwind et al (2002/0155961) in view of Hu et al (6,037,328).

11. Schwind et al is relied upon as set forth above. Specifically, Schwind et al do not teach the inclusion of tyloxapol as an additional surfactant.

12. Hu et al disclose a method and composition for treating contact lens. Specifically, Hu et al disclose the use of an effective amount of a poloxamer and a tyloxapol (col. 2, lines 55-61).

It would have been obvious to one of ordinary skill in the art to include an additional surfactant such as tyloxapol because Hu et al teach that the combination of surfactants has been found to be not only effective in preventing the deposition of lipids, but is comfortable for use in the eye (col. 3, lines 60-65). Therefore, one of ordinary skill would have motivated to include the additional surfactant, tyloxapol in view of the teachings disclosed in Hu et al.

13. Claims 20, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwind et al in view of Groemminger et al (6,872,695).

Schwind et al is relied upon as set forth above. Specifically, Schwind et al do not teach the inclusion of polyvinyl pyrrolidone.

Groemminger et al is relied upon as set forth above. Specifically, Groemminger et al teach the use of polyvinyl pyrrolidone as a thickening agent or pseudoplastic (viscosity affecting) (col. 4, line 28-42) and Schwind et al require the use of substances that affect the viscosity (0032). Therefore, one of ordinary skill in the contact lens art would have include PVP to the compositions of Schwind et al to affect the viscosity of the contact lens composition as suggested by Groemminger et al for the purpose of affecting the shear liquification of gel upon blinking (col. 4, lines 27-29).

### ***Double Patenting***

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140

Art Unit: 1751

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of 6261546; 1-15 of 5858996; 1-12 of 5846919; 1-5 of 5807585; 1-5 of 5683993; 1-11 of 5576276 and claim 1 of 5298182.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in subject matter pertaining to contact lens disinfecting and cleaning compositions comprising polymeric antimicrobial agents; chloride ion concentrations and pH.

16. Claims 1-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/963,972; 11/078,209; 11/212,957 and 11/212,959. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in subject matter pertaining to contact lens disinfecting and cleaning compositions comprising polymeric antimicrobial agents; chloride ion concentrations and pH.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.



Art Unit: 1751

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Necholus Ogden whose telephone number is 571-272-1322. The examiner can normally be reached on M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra N. Gupta can be reached on 571-272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Necholus Ogden  
Primary Examiner  
Art Unit 1751

No  
12-27-05